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FEB 23 1993

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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,219,478 issued on August 26, 1980, was filed on February 11, 1993, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is **NOT** to be considered as notice which may be made in the future pursuant to 35 USC § 156 (d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Mark P. Levy, Esq.
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